PRINCE MAHIDOL AWARD CONFERENCE 2017
ADDRESSING THE HEALTH OF VULNERABLE POPULATIONS FOR AN INCLUSIVE SOCIETY

PS2.5

PARALLEL SESSION 2.5

Access to Medicines:
How to Fix the Broken System

BACKGROUND

The SDG target on UHC (3.8) specifically refers to ensuring that there is “access to safe, effective, quality and affordable essential medicines and vaccines for all”. Perhaps nothing epitomizes vulnerable population’s lack of health coverage more than when they cannot access life-saving medicines and needed diagnostics and medical devices.. The large majority of people who lack access to medicines are those who lack resources and are thus particularly vulnerable. This is compounded by the fact they are more likely to live in communities that have least access to health public health care services. People suffering from diseases such as HIV, Tuberculosis and Leprosy are also stigmatised for their disease, and lack of access to medicines and diagnostics pushes them further to the margins of society.

Lack of access to essential medicines, diagnostics and devices has a more profound impact on resource poor countries and, further, on the poor in these countries, and increasingly, on the disadvantaged in HICs. Available data suggests that poor households spend an average of 9.5% of their household expenditure on medicines, compared with 3.5% of poor households in high income countries (HICs). Such high levels of out-of-pocket (OoP) expenses on medicines, and increasingly now on diagnostics, drive millions of people deeper into a poverty spiral, especially in Low and Middle Income countries. In many LMCs 50-70% of OOP expenses on healthcare are for purchase of medicines. Thus we see a vicious cycle of the vulnerable being less likely to access medicines and lack of access increases vulnerability in already resource starved populations. Economically vulnerable populations are also denied access due to inordinately high prices of medicines and the absence of financial protection in the face of catastrophic expenses’ as well as because medicines that address the health needs of the poor and the vulnerable are just not available.

Such a situation promotes health inequity and requires responses at local, regional and global levels. These responses need to involve national governments, civil society groups including patients’ organisations, and multilateral agencies.

OBJECTIVES

The session is designed to identify drivers that lead to lack of essential access to medicines and diagnostics among economically vulnerable populations and as those suffering from diseases that attract stigma in society. These drivers would include:

- **Health system issues:** Inadequately resourced and inappropriately organised health systems in LMICs that end up promoting OoP expenses as the dominant mode of financing access to medicines, thus pushing people into a downward spiral of indebtedness, increased poverty, and increased vulnerability in the face of lack of secure access to medicines and diagnostics that are essential and life saving.
- **High Medicine prices:** The phenomenon of high monopoly prices for several life saving and essential medicines, thus leading to denial of access to millions of poor patients.
- **R&D Gaps:** The inadequacies in the current research system which does not incentivise the development of new medicines for conditions that differentially affect the poor, including those suffering from what are known as 'neglected diseases'.

The session would, further, explore solutions to address the barriers and challenges inherent in these drivers of poor access to medicines.

MODERATOR

Amit SENGUPTA

Associate Global Coordinator
Peoples Health Movement

India

Dr.Amit Sengupta has trained in medicine. His main interests include issues related to public health, pharmaceuticals policy, and other Science and Technology related policy issues like Intellectual Property Rights.

He has been associated with the Peoples Science Movement in India for the past 30 years, and the Peoples Health Movement in India and at the Global Level for the past 15 years.

Dr.Sengupta has been involved in implementation of a number of action research programmes and research studies in the areas of health, Intellectual Property Rights and on rural industrialization through the Peoples Health Movement and the Centre for Technology and Development, a New Delhi based non-governmental organisation.

He has published a number of papers in peer reviewed journals, including in the Economic and political Weekly, India, the Lancet, The British Medical Journal and the Indian Journal of Medical Ethics.

Currently Dr.Sengupta is the Associate Global Co-ordinator of the Peoples Health Movement (PHM). He has overall responsibility for co-ordination of the Global Health Watch Programme of the Peoples Health Movement. As part of this responsibility he has co-ordinated and also functioned as the Managing Editor of the two recent editions of the Global Health Watch – Global Health Watch 3 (published in 2011) and Global Health Watch 4 (published in 2014). He is currently co-ordinating the publication of Global Health Watch 5, to be published in 2017.

He is associated with a number of other organisations and networks. He is a former All India General Secretary of the All India Peoples Science Network, is a member of the International Council of the World Social Forum.

SPEAKER

Marc LALLEMENT

Head of DNDi's HIV Programme
Drugs for Neglected Diseases Initiative

Switzerland

Dr Marc Lallemant joined DNDi in July 2011 as the Head of Paediatric HIV Programme. Prior to joining DNDi, Dr Lallemant was Senior Researcher at the Institut de Recherche pour le Développement (IRD). In the mid-1980s, he initiated one of the first international research programmes on HIV in pregnant women and children in Africa. After several years at the Harvard School of Public Health as visiting scientist, he moved to Thailand to head the Programs for HIV Prevention and Treatment group (PHPT), a Clinical Research consortium between Chiang Mai University, the Harvard School of Public Health, IRD, and a network of 50 public hospitals throughout Thailand. He was the principal investigator of major NIH funded clinical trials, the results of which have served as the basis for WHO recommendations for PMTCT in resource-limited countries.

He is also involved in the perinatal HIV and paediatric research programme of the Paediatric European Network for the Treatment of AIDS (PENTA) and the International Maternal Paediatric Adolescent AIDS Clinical Trials Group (IMPAACT). Dr Lallemant received his medical degree from Paris 5 University Medical School and his research professorship in Science (HDR) from Paris 7 University, France.

PANELISTS

Lotti RUTTER

Advocacy & Campaigns Manager
Treatment Action Campaign

South Africa

Lotti Rutter is the Head of Policy and Campaigns with the Treatment Action Campaign (TAC) in South Africa. She has worked for the last eight years in the global HIV/AIDS struggle in both South Africa and previously in Europe with the Student Stop AIDS Campaign and STOPAIDS. She specialises in intellectual property law and its impact on access to medicines and currently leads the campaign to reform South Africa's outdated patent laws. She has supported global policy and campaign calls for an alternative system for medicine access and innovation that prioritises the health needs of the people. In addition to treatment access, she focuses on ending the ongoing crisis raging in the South African health system that threatens the lives of many people across the country. Prior to working in global health, she engaged in activism around women's rights, social justice and the environment.

PANELISTS

Giten KHWAIRAKPAM

Project Manager for Community and Policy
TREAT Asia

Thailand

Giten Khwairakpam has been involved in Asia regional advocacy for hepatitis C treatment access which includes efforts to engage people who use drugs, people living with HIV, UNITAID, the Global Fund, facilitating negotiations with originator and generic pharmaceutical companies to address price- and drug distribution-related barriers. Giten also has been providing training to national PLHIV and PWID networks on hepatitis C treatment, access issues and new direct acting agents and their use with antiretroviral therapy. Currently, Giten works with amfAR's TREAT Asia program in Bangkok, Thailand as the Community and Policy Project Manager.

SPEAKERS

Amulya NIDHI

National working group member
Nai Shuruwat / People's Health Movement India

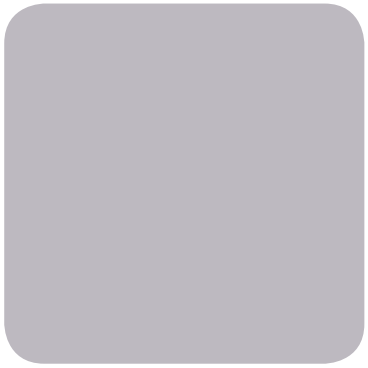
India

PANELISTS

K.M. GOPAKUMAR

Legal Advisor and Senior Researcher
Third World Network

India



SPEAKERS

Tenu AVAFIA

Team Leader
HIV Health and Development Team
United Nations Development Programme

USA

SHORT PAPER

Access to Medicines: How to Fix the Broken System

Background paper Dr Bernard Pécoul, Drugs for Neglected Diseases Initiative (DNDi)
December 2016

There has been growing recognition that the current system for biomedical innovation fails to deliver adapted and affordable health technologies. This crisis was initially understood to affect 'diseases of poverty' in developing countries. But today, despite important progress, the dominant model for financing and incentivizing R&D, which relies primarily on the intellectual property system, is increasingly problematic for all countries – regardless of disease area or income classification.

In recent years and months, the issue of medicines pricing and access to medicines has repeatedly erupted into the media– from editorials arguing that high-price cancer drugs provided insufficient value for money to justify their use, to questions around the pricing model of hepatitis C medicines that make impossible a public health approach to tackling the disease, to outrage over repeated price hikes for older, generic, off-patent drugs and medical devices.

This has undoubtedly facilitated a shift where access and innovation issues now attract attention at the highest policy levels. In late 2015, the UN Secretary-General Ban Ki-moon convened a High-Level Panel "to recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies".

The Panel's report, published in September, includes calls on countries to use TRIPS flexibilities; to initiate talks on an R&D Convention that delinks the cost of innovation from prices; to negotiate a Code of Principles to be adopted for all R&D players to ensure innovation delivers affordable and accessible products; to require greater transparency on R&D costs; and to ensure a public return on tax-payer funded contributions to R&D.

Barely one week later, the UN General Assembly elevated a health issue to crisis level for only the 4th time in its history when it organised the High-Level Meeting on Antimicrobial Resistance in September. Significantly, the political declaration issued at the meeting highlights the need to break the link between the cost of R&D and the sales of life-saving medical tools, and to ensure that public financing for R&D delivers a public return on the investment.

In November 2016, the Lancet Commission on Essential Medicines published a series of recommendations for global essential medicine policies, including policies to access existing high-priced patented medicines, and calling on governments to lead a process towards an R&D policy framework and agreements.

The background paper below – which relies on the analysis contained in a DNDi submission to the High-Level Panel earlier this year – aims to clarify the lessons learnt from DNDi's 13 years of existence, and how these might possibly contribute to fixing the broken system on access to medicines.

DNDi: AN EXPERIMENT IN 'INNOVATION FOR ACCESS'

The Drugs for Neglected Diseases initiative (DNDi) is an international not-for-profit research and development (R&D) organization created in 2003 by Médecins Sans Frontières (MSF) and five public research institutions from India, Brazil, Kenya, Malaysia, France, and WHO/TDR. DNDi was a response to the frustration of being faced with medicines that were ineffective, highly toxic, unavailable, or had never been developed.

In 2001, MSF and partners found that of the 1,393 new drugs brought to market globally between 1975-1999, only 1.1% were for tropical diseases although they represented 12% of the global disease burden. This situation was a result of both market failure, as investments in R&D were guided by market considerations leaving public health needs unaddressed, and public policy failure, as governments had not corrected this situation.

Despite important progress, today the 'fatal imbalance' persists. A 2012 study by DNDi and MSF showed that of the 756 new drugs approved between 2000-2011, 3.8% were for neglected diseases, despite a global disease burden of 10.5%. The 2014 Ebola epidemic and the global threat of antibiotic resistance are stark reminders of the need to steer R&D to respond to public health imperatives. Global attention has also focused on the high prices of hepatitis C and cancer treatments, illustrating that the accessibility and affordability of new health technologies, even when they are developed, is a major concern, including in high-income countries.

DNDi's MODEL

DNDi was an experiment in innovation both in what it did – develop urgently needed treatments for neglected populations – and how it did it – testing an alternative R&D model based on patient needs, not profit maximization.

DNDi's funding model does not require the organization to recoup R&D investments or finance its future research through the sales of products or revenues generated by intellectual property (IP). Public and private contributions pay for the cost of R&D upfront, allowing DNDi to independently identify needs, gaps, and priorities based on patient needs; promote sharing of research knowledge and data; and price products at the 'lowest sustainable price.' As such, the DNDi model is a practical illustration of how R&D can be conducted in the public interest, if a de-linked approach is implemented.

To date, with total expenditures of US$285 million, DNDi has delivered six new treatments for four diseases (malaria, sleeping sickness, visceral leishmaniasis, and Chagas disease) that are affordable, adapted, and non-patented. For example, 400 million treatments of the anti-malarial artesunate-amodiaquine (ASAQ) have been distributed. Developed in partnership with Sanofi and others in 2007, ASAQ is available for less than US$1 per treatment course for adults (less than 50 cents for children), was prequalified by WHO in 2008, and is registered in 35 countries. The technology was transferred to a manufacturer in Tanzania. In addition, DNDi has created a robust pipeline with 30 R&D projects covering six disease areas, including 15 potential new chemical entities (NCEs).

Some key pillars of DNDi's model include:

<u>1) Patients' needs at the center of the R&D process</u>

Therapeutic impact is the most important driving force behind DNDi's work. DNDi's founding partners, particularly from endemic countries, MSF, and two patient representatives on the Board ensure the organization remains rooted in the reality of patients' needs.

DNDi develops target product profiles which describe the ideal specifications needed for a treatment, considering the needs of the patients and the characteristics of the related health system, and which drive all R&D activities. Because they are tailored to patient needs from the start, products developed by DNDi are, by design, adapted to 'field conditions' and aim for maximum affordability.

2) Scientific access to data and knowledge and patient access to medicines

IP rights can create roadblocks throughout the innovation cycle, limiting the possibility of collaboration, follow-on R&D, production, or equitable access to end-result products. To address these barriers, DNDi's IP policy is based on two guiding principles that inform all contract negotiations: the need to ensure that drugs are affordable and accessible in an equitable manner to patients who need them; and the desire to develop drugs as global public goods.

Using its negotiating experience with pharmaceutical companies and others, DNDi has defined 'gold standard' licensing terms to ensure equitable and affordable access to treatments:

- Perpetual royalty-free, non-exclusive, sub-licensable licenses to DNDi in the contractually defined target disease(s);
- Worldwide research and manufacturing rights;
- Commitment to make the final product available at cost, plus a minimal margin, in all endemic countries, regardless of income level;
- Non-exclusivity, enabling technology transfer and local production to multiply sources of production and decrease price of product.

Licenses can be more difficult to negotiate in cases of pre-existing licenses, prospects of returns on investment from sales in certain markets, and/or significant investments of a private partner in early stages of development. A global normative framework to ensure equitable access to research knowledge and end products would speed negotiations, and enhance efficiency and affordability.

Where IP barriers exist (e.g. HCV), DNDi uses available IP flexibilities for research purposes (e.g. experimental use and/or research exemptions), and supports the use of TRIPS flexibilities to enable production/importation of products.

3) Decreasing R&D costs through partnerships and collaboration

DNDi does not have its own laboratories or manufacturing facilities, and consequently cannot function without the engagement of partners. Acting as a 'conductor of a virtual orchestra,' DNDi leverages partners' assets, capacities, and expertise to implement projects at all stages of the R&D process, integrating capabilities from academia; public research institutions; NGOs and other PDPs; governments; and pharmaceutical and biotechnology companies.

Not all R&D efforts should function virtually, but the important lessons are that openness and collaboration are critical to reducing the time it takes to deliver new technologies and decreasing the overall cost of R&D. In 2014, DNDi published case studies to document the actual expenditures

associated with several DNDi products. DNDi estimates its direct costs to range from US$6.5-22 million for an improved treatment, and US$33-44 million for a NCE. Applying the usual attrition rate in the field of infectious diseases, the cost to develop an improved treatment would be US$11-44 million and US$110-165 million for an NCE. Deeper analysis of R&D costs should be conducted, particularly to fairly quantify in-kind contributions of partners. Although it is difficult to compare R&D costs between different business models, DNDi's experience indicates that innovative models can both deliver rapidly for patients and potentially be more efficient than the traditional pharmaceutical business model.

IMPLICATIONS FOR ACCESS AND INNOVATION

Over the past decade, there have been positive trends in the global health R&D field, including new resources from public and private donors; new incentives and financing mechanisms; increased interest in open innovation models; and new R&D initiatives from governments, academic consortia, and the pharmaceutical industry as well as PDPs.

But the patchwork of 'solutions' that have emerged to date is still ad hoc and highly fragmented. Scientific progress has been largely incremental and the situation for neglected patients has not fundamentally changed. Private sector engagement is still being driven primarily by public relations or corporate social responsibility concerns. Funding is insufficient and unsustainable, with unhealthy dependence on a handful of donors, often driven by national interests or a charity-based approach. Many new incentive mechanisms, such as the FDA Priority Review Voucher, though promising, need to be amended to prevent abuse, drive genuine innovation, and ensure access and affordability. There is no global body in place for identifying needs, gaps, and priorities, no effective monitoring and coordination of R&D efforts to maximize scientific collaboration and reduce wasteful duplication. And there is no overarching framework of globally agreed norms to ensure sharing of data and knowledge, and ensure the affordability of end products.

It is time to transform individual successes into a more systematic and sustainable approach for all diseases of public health importance. DNDi's collaborative model has shown at a small scale that alternative approaches to R&D that address pressing public health needs are possible. However, individual initiatives cannot be the only solution to the problem. To fully address the scale of public health needs, public leadership is needed to redefine the 'rules of the game.'

A PUBLIC HEALTH-CENTRED GLOBAL BIOMEDICAL R&D SYSTEM

DNDi recommends governments adopt a series of progressive policy steps to re-orient the biomedical R&D system so that it responds to patient needs:

Governments should implementing and use TRIPS flexibilities to allow development of and access to medical technologies.

They should support and encourage the participation of industry and academia in approaches to access medical technologies and data, e.g. disclosure of research data and R&D costs, pre-competitive research platforms, and patent pools that further develop licensing conditions to include all affected countries.

And they should launch a high-level political process aimed at creating one or more binding global agreement(s) based to ensure the financing, coordination, and norms required for the discovery, development, and delivery of appropriate and affordable innovations of public health importance. The following elements are critical to any global biomedical R&D agreement(s):

(1) Needs-driven

R&D that addresses priority public health needs must be the overarching objective. Independent body or bodies to identify R&D needs and gaps, (such as the WHO Global Health R&D Observatory), establish clear priorities, and coordinate efforts to enhance collaboration and reduce duplication will be necessary.

(2) Adequate, sustainable public financing based on the principle of delinkage

R&D requires adequate, sustainable funding from governments, which should be available at the national, regional, and international levels, as well as mechanisms to incentivize innovation and secure access, based on the principle of delinkage. Funding and incentive mechanisms should promote open, collaborative approaches that aim from the start to deliver affordable products efficiently. In order to best direct funding to agreed priorities, at least some portion of health R&D funding should be pooled.

(3) Global norms that ensure innovation and access, accelerating the R&D process and decreasing R&D costs

Public funding for R&D should be tied to the adoption of fundamental norms, which include:

- Delinkage, to ensure public health focus and access, which applies across the innovation cycle and can be implemented in a number of ways (e.g. grants, prizes);
- Accessibility, meaning universal and equitable availability and affordability of health technologies for individuals and the health systems that serve them;
- Openness, transparency, and access to knowledge, meaning the greatest possible sharing of research knowledge to ensure efficiency and collaboration, and transparency of R&D costs;
- Pro-public health IP management and equitable licensing – concerning the availability, scope, and use of research tools and affordability of end products – to enable research and the fruits of innovation to be global public goods;
- Scientific and technological cooperation to harness expertise in both developed and developing countries, encourage collaboration between research centers, and facilitate technology transfer;
- Essential regulatory standards to expedite access for patients, while ensuring that new treatments are safe, effective and of quality, reduce R&D costs linked to regulatory approvals, and strengthen regulatory capacity.